JUN 17 2004

510(k) SUMMARY
As required by the Safe Medical Devices Act of 1990

A-SILICONE

IDENTIFICATION OF THE LEGALLY MARKETED PREDICATE DEVICES

Bisco TWINZ VPS
Heraeus Kulzer FLEXITIME

The two indicated predicate devices are addition reaction silicone impression materials also known as vinyl polysiloxane impression materials. The viscosity range is similar to A-SILICONE in that they contain examples of putty based, heavy body, medium body and light body products intended for identical uses in dentistry, that is, for taking impressions of teeth, prepared teeth, oral soft tissue, and bite registrations.

SUBSTANTIAL EQUIVALENCE Summary

	Cosmedent A-SILICONE	Heraeus Kulzer FLEXITIME[1-2]	Bisco TWINZ VPS[3-4]
Intended Use	Auto-mix, elastomeric dental impression material	Auto-mix, elastomeric dental impression material	Auto-mix, elastomeric dental impression material
Composition	Addition reaction, silica filled polydimethyl siloxane	Addition reaction, silica filled polydimethyl siloxane	Addition reaction, silica filled polydimethyl siloxane
Clinical properties	Multiple viscosities permitting dual-mix, monophase, and putty-wash techniques	Multiple viscosities permitting dual-mix, monophase, and putty-wash techniques	Multiple viscosities permitting dual-mix, monophase, and putty-wash techniques
Viscosities or grades available	Putty, heavy body, medium body, and light body	Putty, Heavy body, medium body, and corrective light body	Putty, heavy body, medium body, light body, and extra light body

A-SILICONE
510(k) SUMMARY (cont)

DESCRIPTION OF THE APPLICANT DEVICE – A-SILICONE

A-SILICONE is vinyl polymethyl siloxane dental impression material composed of four viscosities or bodies including: putty, heavy body, medium body, and light body. The material is suitable for use in traditional double mix technique, monophase technique, and putty-wash technique as well as unique combinations of techniques.

MATERIALS SPECIFICATIONS

PROPERTY	Putty	Heavy Body	Medium Body	Light Body
Consistency, ISO 4823	heavy body type 0	heavy body type 1	Medium body type 2	Light body type 3
Color	light green	turquoise	lilac	pink
Working time including mixing	45 seconds to one minute			
Time in the mouth	two minutes			
Total setting time, minimum	2 minutes – 45 seconds			
Strain in compression, %	<2	<4	<5	<5
Recovery from deformation, %	>99.4	>99. 4	>99.6	>99.6
Linear dimensional change, %, max	0.2	0.15	0.15	0.15
Hardness Shore A	70	50	45	40

INTENDED USES OF THE APPLICANT DEVICE

- A-SILICONE is a dental impression material intended to be placed on an impression tray and used to reproduce the structures of a patient's teeth and gums.
- A-SILICONE is also intended to be used as a bite registration or occlusal registration material.

James L. Sandrik, Ph.D.

Cosmedent, Inc.
Suite 2500
401 N. Michigan Ave.
Chicago, Illinois 60611

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 17 2004

Dr. James L. Sandrik
Director of Regulatory Affairs
Cosmedent, Incorporated
401 North Michigan Avenue, Suite 2500
Chicago, Illinois 60611

Re: K041229
Trade/Device Name: Multiple (A-Silicone)
Regulation Number: 872.3660
Regulation Name: Impression Material
Regulatory Class: II
Product Code: ELW
Dated: May 7, 2004
Received: May 10, 2004

Dear Dr. Sandrik:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K041229

Device Name: MULTIPLE (**A-SILICONE**)

Indication For Use:

- A-SILICONE is a dental impression material intended to be placed on an impression tray and used to reproduce the structures of a patient's teeth and gums.
- A-SILICONE is also intended to be used as a bite registration or occlusal registration material.

Prescription Use___X_____ AND/OR Over-The-Counter Use____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K041229